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10/749,822

12/31/2003

John Pafford

1842-0029

9366

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7590

05/16/2006

MAGINOT, MOORE & BECK, LLP
CHASE TOWER
111 MONUMENT CIRCLE
SUITE 3250
INDIANAPOLIS, IN 46204

EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/749,822 | Applicant(s) PAFFORD ET AL. | |
| | Examiner Mary Hoffman | Art Unit 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/28/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 1-8 and 15-20 are objected to because of the following informalities: In claim 1 and 15, please change in the preamble "the spine" to --a spine--, to be clearer for examination purposes. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 15-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Jammet et al. (French Patent Application Publication No. 2 796 828, see corresponding U.S. Patent No. 6,123,706 for translation)

Jammet et al. disclose a dynamic stabilization system comprising a stabilization element (FIG. 1, ref. #18) capable of spanning between two vertebrae, at least two bone anchors (FIG. 1, ref. #1, 2), each having a bone engagement portion (threaded section of ref. #1,2), and at least two connectors capable of connecting a corresponding one of the bone anchors to the stabilization element (ref. #16- left side of device, and #19,9,7,8-right side). At least one of the connectors includes a flexible element (FIG. 1, ref. #7) between the bone anchor and the stabilization element capable of permitting

Art Unit: 3733

relative pivoting there between and an adjustment element for adjusting the flexibility of the flexible element. The connector includes a bearing member (ref. #9,7,8) attached to the stabilization element, the bearing member including the flexible element (FIG. 1, ref. #7). The stabilization element includes an elongated spinal rod (ref. #18); the bearing member is a rod-end bearing including a rod engagement portion (ref. #20) and the flexible element is a bearing element of the rod end bearing. The bearing element is received within a bearing race (FIG. 1, ref. #9,8) of the rod end bearing and the adjustment element (FIG. 1, ref. #6) is arranged to compress the bearing element within the bearing race. The rod engagement portion includes a bore (ref. #20) capable of receiving a portion of the spinal rod therein and a set screw (FIG. 5, ref. #33) for clamping the spinal rod within the bore. The at least one of the bone anchors includes a stem having a threaded portion (ref. #5); and the flexible element includes a bore (ref. #11) capable of receiving the stem there through; and the adjustment element includes a nut (ref. #6) engaging the threaded portion and arranged to compress the flexible element as the nut is threaded onto the threaded portion. The at least one of the bone anchor includes an intermediate portion (FIG. 1, ref. #3) between the stem and the bone engagement portion, the intermediate portion capable of supporting the flexible element so that the flexible element is compressed between the intermediate portion and the nut when the nut is threaded onto the threaded portion. The anchor of the connector is capable of substantially rigidly connecting one of the bone anchors to the stabilization element. With regard to the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable

Art Unit: 3733

over Jammet et al. which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claims 15-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Lahille et al. (U.S. Patent No. 5,380,325).

Lahille et al. disclose a dynamic stabilization system comprising a stabilization element (FIG. 1, ref. #1) capable of spanning between two vertebrae, at least two bone anchors (FIG. 1, ref. #2), each having a bone engagement portion, and at least two connectors capable of connecting a corresponding one of the bone anchors to the stabilization element. At least one of the connectors includes a flexible element (FIG. 1, ref. #25) between the bone anchor and the stabilization element capable of permitting relative pivoting there between and an adjustment element for adjusting the flexibility of the flexible element. The connector includes a bearing member attached to the stabilization element, the bearing member including the flexible element (FIG. 1, ref. #25, 26, 3 and 23). The stabilization element includes an elongated spinal rod; the bearing member is a rod-end bearing including a rod engagement portion and the flexible element is a bearing element of the rod end bearing. The bearing element is

Art Unit: 3733

received within a bearing race (FIG. 1, ref. # 26) of the rod end bearing and the adjustment element (FIG. 1, ref. #24) is arranged to compress the bearing element within the bearing race. The rod engagement portion includes a bore capable of receiving a portion of the spinal rod therein and a set screw (FIG. 2, ref. #24) for clamping the spinal rod within the bore. The at least one of the bone anchors includes a stem having a threaded portion; and the flexible element includes a bore capable of receiving the stem there through; and the adjustment element includes a nut engaging the threaded portion and arranged to compress the flexible element as the nut is threaded onto the threaded portion. The at least one of the bone anchor includes an intermediate portion (FIG. 1, ref. #21) between the stem and the bone engagement portion, the intermediate portion capable of supporting the flexible element so that the flexible element is compressed between the intermediate portion and the nut when the nut is threaded onto the threaded portion.

Response to Arguments

Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 4/28/2006 with regard to claims 15-20 have been fully considered but they are not persuasive.

In response to applicant's arguments that the Lahille et al. patent does not include a bearing race mounted within a bearing member, as explained above, the examiner is considering the components ref. #25, 26, 3 and 23 to be the bearing

member, and the bearing race as ref. # 26. A “race” is defined as a track or channel in which something rolls or slides (Merriam-Webster Dictionary). The flexible element is capable of sliding between the channel created between washers ref. #26. Furthermore, the definition of a “bearing race” is “...one of the two steel rings on either side of the ball or roller” (DICTIONARY OF AUTOMOTIVE TERMS:

<http://www.motorera.com/dictionary/car-dic.htm>). Therefore, using this definition, the examiner is considering the washers #26 as the bearing race, because the bearing races are defined as the rings on either side of the roller bearing, not the roller bearing itself that would also include the roller or ball. In addition, while applicant argues a “bearing member” is conventionally understood in the art, it is noted that the term “bearing member” can be broadly interpreted as any member that bears another object, or supports the weight of another object. Furthermore, since applicant has not indicated that the bearing member is monolithic, ref. #23 has been now included as part of the bearing member in the current rejection to meet the limitations set forth in the claims (see 102(b) rejection above). From applicant’s arguments, it appears that applicant’s intention is to claim a rotating support (the flexible element) placed between moving parts (the bearing races) to allow them to move easily. Applicant’s argument that the Lahille et al. reference does not include these features of Applicant’s invention, however, the limitations on which the Applicant relies (i.e., Applicants definition of bearing member, and the structure associated with the bearing member components) are not sufficiently stated in the claims. Therefore, it is irrelevant whether the reference includes those features or not.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

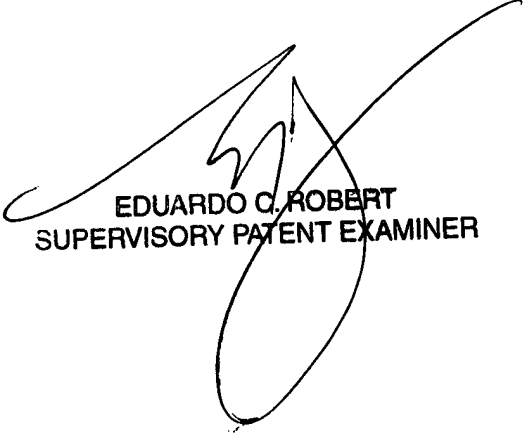
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MCH



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER